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K132763

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510 (K) SUMMARY
ADVANCED VIEWER

IN ACCORDANCE WITH REQUIREMENTS OF 21 CFR PART 807.92

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	8/30/2013
Device:	Advanced Viewer
Trade name:	Advanced Viewer
Common/Classification Name:	Picture archiving and communications system
Main Predicate Device:	CONi (K130624)
Secondary Predicate Device:	iPlan (K113732)
Device classification name:	system, image processing, radiological
Regulatory Class:	Class II
Regulation Number:	892.2050
Product Code:	LLZ
Intended use:	Advanced Viewer is a web based software for medical professionals that provides doctors with tools for secure online image (DICOM) review including measurement functions and the display of voxel objects. It is not intended for detailed treatment planning, treatment of patients or the review of mammographic images. It is also not intended to be used on mobile systems.
Device description:	Advanced Viewer is integrated in the online collaboration platform Quentry to share, discuss and transfer medical image data. The viewer provides capabilities to visualize medical images (DICOM) that have been uploaded to the platform before. Quentry is a software platform consisting of a set of server-based components providing functions for transfer and storage of medical data, as well as user access via a web-based portal for data management, sharing, and download. The platform is integrated with desktop and server-based applications for upload and download of medical data from workstations and network-based image archive servers. The platform also provides interfaces for integration of third-party systems and applications. Quentry platform is an FDA class I

product.

Advanced Viewer is generally used by medical professionals such as doctors, their assistants or nursing staff, within a clinic or at a doctor's office, or even at home.

Typical use cases of the embedded viewer together with the functionality of the web portal are:

- Physicians asking/providing colleagues for/with 2nd opinion
- Physicians refer patients to other hospitals and send pictures upfront
- Expert service: Several hospitals share one radiology department
- Basic diagnostic tasks (measurement function and display of structures)

Device Features

Advanced Viewer provides the following functions

Load and import DICOM images	Load DICOM images from cloud database
View DICOM images	Viewer converts DICOM images to PNG format for viewing
Adjustment (pan, zoom, window, color scheme adjustment)	Review patient data with various adjustment
Reconstruction	Review patient data from different orientation
Measurement – distance	Viewer provides distance measurement between two arbitrary points
Measurement – Point	Viewer provides gray level measurement for an arbitrary point
Voxel object	Review imported DICOM objects
Fused images	Review aligned patient data, e.g. CT, PT and so on
Cine loop playing	Display multiframe DICOM images

Substantial equivalence:

Both Advanced Viewer and CONi (the main predicate device) are web-based/cloud-based software for viewing DICOM images. Both of the proposed and predicate devices are to be used with any computer with appropriate internet connection. Equivalent with the predicate device, Advanced Viewer is software installed in a web server that will communicate with the client via internet connection. Advanced Viewer utilizes encrypted browser communication. Image viewing and manipulation are provided by both devices.

Whereas Advanced Viewer provides more viewing features than CONi as discussed in the substantial equivalence table; Advanced Viewer and iPlan (the secondary predicate device) provide identical functionalities of viewing, adjusting, and measuring DICOM images. Equivalent to the predicate device, Advanced Viewer is intended for medical professionals to view and adjust DICOM images. Advanced Viewer and iPlan use the same software framework.

As a conclusion Advanced Viewer has similar functionality, intended use, technological characteristics, and typical users as the predicate devices.

Hence Advanced Viewer does not introduce any new issues concerning safety and effectiveness, and is substantial equivalent to the predicate devices.

Conclusion:

CONi and Advanced Viewer have similar functionality. Advanced Viewer provides further viewing features which are substantially equivalent with iPlan. These extended viewing features neither constitute any new intended use, nor raise any questions that affect safety and effectiveness, since they provide users with more advanced functions viewing images but no function more than viewing..

Compared with iPlan, Advanced Viewer runs on a different platform. However, since Advanced Viewer and iPlan provide identical functionalities and utilize the same software framework, Advanced Viewer does not introduce any issues concerning safety and effectiveness.

Advanced Viewer has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Hence Advanced Viewer does not introduce any new issues concerning safety and effectiveness, and is substantially equivalent to the predicate devices.

Verification/validation summary:

Verification

The verification of the System Advanced Viewer has been carried out thoroughly both at the top level and on the underlying subsystems. The verification was done to demonstrate that the design specifications are met.

Non-clinical validation

The validation contained usability tests which should ensure that workflows or user interface result in a useful interface.

All test reports were finally rated as successful according to their acceptance criteria. The non-clinical validation has been performed with software and units that are considered equivalent to the final version of the product, as warranted by 21 CFR 820.30 (g) and which have the UI as planned for the release.

The user tests were done in combination with the Quentry.com Portal 2.0.1 which is developed and released by Voyant Health, a Brainlab company. The Advanced Viewer workflow included also patient selection as interface between Quentry.com Portal and the Advanced Viewer.

Intended operational Environment

Standard computer with internet connection and mouse.

Operating System
The following versions or higher:

- Windows XP
- Mac OS X

Browser
The following 32 bit versions or higher:

- Internet Explorer 8
- FireFox 3.x

- Chrome 10
- Safari 5

Microsoft® Silverlight® 5 Plugin needed

Hardware

- 2GB RAM recommended
- Screen resolution: 1024x768 or higher
- Mouse with scroll wheel recommended

Network

- Internet connection with at least 1Mbit/sec (2 Mbit/sec recommended). The internet connection
- must be stable. You may need to restart the viewer if the internet connection is unstable.
- Firewall with open outbound port 80/443 (http and https)

Known Exceptions

- 64bit browsers are not supported by Microsoft® Silverlight®

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Brainlab AG
% Mr. Alexander Schwiersch
Regulatory Affairs Manager
Kapellenstrasse 12
85622 Feldkirchen
GERMANY

Re: K132763
Trade/Device Name: Advanced Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 10, 2014
Received: January 13, 2014

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132763

Device Name
Advanced Viewer

Indications for Use *(Describe)*
Advanced Viewer is a web based software for medical professionals that provides doctors with tools for secure online image (DICOM) review including measurement functions and the display of voxel objects.
It is not intended for detailed treatment planning, treatment of patients or the review of mammographic images. It is also not intended to be used on mobile systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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